

REMARKS

Discussion of Specification and Claim Amendments

As a convenience for the Examiner, a complete set of the pending claims is attached to this Amendment.

Since claims 50-123 are added, claims 31-123 will be pending following entry of this Amendment.

Several changes have been made in the specification to improve its form. These changes are essentially editorial in nature and do not constitute the addition of new matter. In particular, the specification amendments merely correct typographical and grammatical errors.

Claims 31-36, 41-46, 48, and 49 are amended to correct typographical errors, to sharpen the claim language, or to make cosmetic changes. The amendments to these claims are not narrowing amendments. The basis for the amended claim language may be found throughout the original specification and claims.

New claims 50-123, directed to embodiments, are supported by the specification and original claims, for example, at specification page 10, lines 1-2, and originally filed claim 6.

No new matter has been added.

Discussion of Rejection under 35 USC 112, second paragraph

Claims 31-35, 45, and 47 are rejected under 35 USC 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The rejection is respectfully traversed.

Claim 31 is rejected for containing the terms “substantially completely.” Applicants respectfully submit that the use of the term “substantially” does not render claim 31 vague.

The degree of precision necessary to satisfy § 112, second paragraph, is a function of the subject matter. *Miles Laboratories, Inc., v. Shandon, Inc.*, 997 F.2d 870, 27 USPQ2d 1123 (Fed. Cir. 1993), *cert. denied*, 510 U.S. 110 (1994). Claims are often drafted using terminology that is not numerically precise. As long as the result complies with the statutory requirement, that

practice is permissible. *PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 48 USPQ2d 1351 (Fed. Cir. 1998). The term “substantially” is a descriptive term commonly used in patent claims to “avoid a strict numerical boundary to the specified parameter.” *Pall Corp. v. Micron Seps.*, 36 USPQ2D 1225, 1229 (Fed. Cir. 1995). Terms such as “substantially” are “ubiquitous in patent claims.” *Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 927 (1988). See also *Ecolab Inc. v. Envirochem Inc.*, 60 USPQ2d 1173 (Fed. Cir. 2001) (“substantially uniform” avoids the strict 100% nonuniformity boundary).

The nature of the subject matter recited in claim 31 is such that the use of “substantially” is fully justified. There is no need to provide a percent value. In view of the foregoing, the indefiniteness rejection of claim 31 should be withdrawn. Claims 32-35, 45, and 47 also should not be rejected on this basis.

Claim 45 is rejected for containing the term “suitable.” Applicants respectfully submit that the use of the term “suitable” does not render claim 45 vague. The use of the term “suitable” is commonly accepted and is clear as used in the claim. Claim 45 is dependent upon claim 31 or claim 36. The method of claim 45 defines a dispersion suitable for intravenous injection having a microdroplet matrix of mean diameter from about 50 nm to about 1000 nm.

Claim 47 is rejected for containing the term “medium.” Applicants respectfully submit that the use of the term “medium” does not render claim 47 vague. In particular, medium chain triglyceride finds support throughout the specification, for example, on page 10, lines 1-2. Further, medium chain triglycerides are well known in the art, and refer to C₈ to about C₁₄ fatty acid medium chain triglycerides. The Examiner is referred to the Attachment entitled “MIGLYOL® 810, 812, 818, 829, 840: Neutral Oils for Pharmaceuticals and Cosmetics,” (Product Information 26.13.035e/03/00, Condea Chemie GmbH), which discloses a medium chain triglyceride.

Therefore, the rejections with respect to claims 31, 45, and 47 should be removed. Likewise, the rejections of claims 32-35, which are dependent upon claim 31, should also be removed.

In re Appln. of MISHRA et al.
Application No. 09/820,371

Discussion of Rejection under 35 USC 112, first paragraph

Claims 31-33, 35-38, and 40-49 are rejected under 35 USC 112, first paragraph. This rejection is respectfully traversed.

While the paragraph beginning at specification page 11, line 9 refers to formulations having a viscosity from about 1.5 to 8 centipoises, this range is not an essential element of claims 31-33, 35-38, or 40-49. This range constitutes an important range; however, these claims are not limited to that range. As stated in the specification, "it is believed that such high viscosities may be partly responsible for minimizing the tissue-irritating effect of the formulation." (See specification page 11, lines 12-13).

Therefore, the rejections of claims 31-33, 35-38, and 40-49 is erroneous and should be removed.

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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